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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,255	03/19/2004	Chih-Ming Chen	141-201B	7485

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,255	CHEN ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment and Declaration under 37 C.F.R. 1.130 filed 01/18/05.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of USPN 6,733,778 ('778). Although the conflicting claims are not identical, they are not patentably distinct from each other because '778 claims a stable pharmaceutical dosage formulation for oral administration comprising a plurality of enteric coated pellets wherein each pellet consists essentially of: a) a core consisting-essentially of 10-50 weight percent based on the total weight of the core of omeprazole or a pharmaceutically acceptable salt thereof, a surface active agent, a filler, a binder and 0.5 to 10 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the

alkaline agent is selected from the group consisting of lysine and arginine; and b) a coating layer surrounding the core that consists essentially of an enteric coating agent, 5 to 50 weight percent based on the total weight of the coating layer of an inert processing aid and optionally a plasticizer wherein the enteric coating layer is applied directly to the omeprazole containing core without a separating layer between the omeprazole containing core and enteric coating layer; and because '778 claims a stable pharmaceutical dosage formulation for oral administration comprising a plurality of enteric coated pellets wherein each pellet consists of essentially of: (a) a core consisting essentially of: (a) an inert core and (b) a drug layer consisting essentially of 10-50 weight percent based on the total weight of the core of omeprazole or a pharmaceutically acceptable salt, a surface active agent, a filler, a binder and 0.5 to 10 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine; and (b) a coating layer surrounding the core that consists essentially of an enteric coating agent, 5 to 50 weight percent based on the total weight of the coating layer of an inert processing aid and optionally a plasticizer wherein the enteric coating layer is applied directly to the omeprazole containing core without a separating layer between the omeprazole containing core and enteric coating layer and wherein said pharmaceutical dosage formulation is a capsule. Enteric coating agent is found in claims 5 and 13. Inert processing aid is found in claims 6 and 14. Accordingly, the claims are anticipated by '778.

It is noted that there are number of applications appear to be potential double patenting based on overlapping, similar, or like subject matters. For example, 6,602,522; 6,174,548; and 6,096,340. Therefore, it is the applicant's obligation to submit terminal disclaimers for all applications requiring terminal disclaimers. The examiner puts applicants on notice; failure to comply with the requirement will result in a final rejection of the next office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-27 are rejected under 35 U.S.C. 103(a) as being obvious over Lundberg et al. US 6,013,281.

Lundberg teaches pharmaceutical oral dosage form comprising a core that contains a proton pump inhibitor, one or more alkaline reacting compounds (alkaline

agent), excipient; and an enteric coating layer (see abstract). The proton pump inhibitor in the core is mixed with alkaline agent, filler, binder, lubricant, disintegrant, surfactant, and other pharmaceutically acceptable additives (column 8, lines 11-25, and examples). The core can be in the form of pellet or tablet (column 6, lines 27-29; and column 8, lines 49-50). Proton pump inhibitor includes omeprazole or it's alkaline salts (column 4, lines 29-35; example 2; and claims 1-3). Alkaline agent includes lysine and arginine (column 6, lines 50-55). The enteric coating layer comprises enteric coating material such as cellulose acetate phthalate (column 7, lines 28-38), plasticizer, and talc (column 7, lines 39-53, and examples 5-6). The amounts of the core materials can be found in examples 5 and 6, which if converted into percentage weights, would fall within the claimed ranges.

It is noted that Lundberg teaches a separating layer, however, that separating layer is nothing but a salt that formed in situ during the enteric coating by a reaction between the enteric coating polymer and one or more alkaline reacting compounds in the core (column 6, lines 14-54, and examples). Accordingly, the burden is shifted to the applicant to provide data showing detrimental effect of the present of the separating layer that formed in situ during the enteric coating. The use of the transitional phrase "consisting essentially of" is noted, however, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristics" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). In the instant case, the composition taught by Lundberg uses the same active agent; the same filler,

binder, and surfactant; the same alkaline agent; and the enteric coating agent, plasticizer, and inert processing aid to obtain the same result, namely an oral pharmaceutical composition of omeprazole that has stability properties (column 4, lines 29-67). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Lundberg is different in the sense that it does not teach the claimed amount of the inert processing aid. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable amount of an inert processing aid to obtain the claimed invention, because Lundberg teaches an enteric coating layer that has flexibility and hardness properties without any significant effect on the acid resistance (column 7, lines 40-48).

Response to Arguments

Applicant's arguments filed 01/18/05 have been fully considered but they are not persuasive.

Applicant argues that Lundberg at column 7, lines 6-26, suggest that a large amount, *i.e.*, 85% of the core weight, of an alkaline agent may be required. Further, example 1 is only one example describes an omeprazole pellet which employs arginine or lysine. Therefore, Lundberg does not teach the claimed amount of arginine in the core. In response to applicant's argument, first, the large amount *i.e.*, 85% disclosed in column 7, lines 6-26 is an example of an upper limit of alkaline agent that may possibly be used. However, column 7, lines 6-13, discloses alkaline agent can be used as little as 0.1 mmol/g dry. Example 1 shows the use of 4.4 mmol/g of arginine, which is about 58% by weight of the core; and example 5 shows .88 mmol/g, which is about 9.6% by weight of the core. Secondly, in response to applicant's argument that example 1 is only one example describes an omeprazole pellet which employs arginine or lysine, it is noted that example 5 also describes the pellet comprising proton pump inhibitor containing the claimed amount of lysine in the core. Although pantoprazole is used in place of omeprazole, it would have been obvious for the skilled artisan to, by routine experimentation modify example 5 using omeprazole, because Lundberg teaches the equivalent of proton pump inhibitor such as omeprazole, lansoprazole, or pantoprazole. Accordingly, Lundberg does teach the claimed amount of alkaline agent.

Applicant argues that Lundberg does not teach the claimed amount of inert processing aid in the coating layer, and thus, the claimed invention is patentable over

Lundberg. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Applicant submitted Exhibit B, which is an article entitled "Effects of Solids-Polymer interactions on the Properties of Some Aqueous-Based Tablet Film Coating Formulations" to show criticality of the claimed amount of inert processing aid. The Exhibit has been fully considered, but not persuasive because there is no evidence indicating the claimed amount of inert processing aid is critical in obtaining a stable omeprazole pellet. It is noted that Lundberg also recognizes the need of achieving a stable omeprazole composition (see column 4, liens 58-67).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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